REMARKS

Revocation of Power of Attorney

Applicant is enclosing herewith a Revocation of Power of Attorney and Appointment of New Attorney naming BRUCE H. TROXELL as attorney of record in this patent application. It is requested that all further correspondence regarding this matter be forwarded to TROXELL LAW OFFICE PLLC at the address listed on the enclosed form. A CHANGE OF ADDRESS form is also submitted herewith.

Claim Rejections

Claim 3 is rejected under 35 U.S.C. §112.

Claims 1-2 are rejected under 35 U.S.C. §103(a) as being unpatentable over Cunningham et al. (6,306,104) in view of Boecker et al. (6,966,880). Claim 3 is rejected under 35 U.S.C. §103(a) as being unpatentable over Cunningham et al. in view of Boecker et al. as applied to claim 1, and further in view of LeDaughn et al. (6,197,040).

Substitute Specification

It was felt that the most expeditious way of correcting the numerous grammatical and idiomatic inaccuracies present in the specification as filed was the preparation of a Substitute Specification. The Substitute Specification is attached hereto and is accompanied by a marked-up copy of the original specification which indicates the changes made thereto by the Substitute Specification. No "new matter" has been added to the original disclosure by the Substitute Specification. Entry of the Substitute Specification is respectfully requested.

Abstract of the Disclosure

Applicant is submitting a substitute Abstract of the Disclosure for that originally filed with this application to more clearly describe the claimed invention. Entry of the Substitute Abstract of the Disclosure is respectfully requested.

Drawings

It is noted that the Examiner has accepted the drawings as originally filed with this application.

New Claims

By this Amendment, Applicant has canceled claims 1-3 and has added new claims 4-5 to this application. It is believed that the new claims specifically set forth each element of Applicant's invention in full compliance with 35 U.S.C. § 112, and define subject matter that is patentably distinguishable over the cited prior art, taken individually or in combination.

The new claim is directed toward a biosensor monitor for use in measuring bioanalyte comprising: a test strip (20); a lancet (40); a lower protective cover (18); a lancing device (30) having: an inner tube (31) connected to the lower protective cover and having inner tube teeth (313); a smaller spring (32); a connecting rod (34) inserted into an interior of the inner tube and having a protrusion (344), the smaller spring biasing the connecting rod outwardly from the interior of the inner tube, the inner tube teeth engaging with and forcing the connecting rod to rotate within the inner tube as the connector rod moves axially within the inner tube; an adapter (33) located between the smaller spring and the connecting rod, the adapter connecting the connecting rod to the smaller spring; a larger spring (38) located around the inner tube; an outer tube (36) having an outer tube slope (364) and outer tube teeth (363) located on an inner wall thereof, the inner tube is partially inserted into an interior at a first end of the outer tube, the connecting rod, the adapter and the smaller spring are located in the interior of the outer tube, the protrusion of the connecting rod engaging the outer tube teeth and the inner tube teeth, the outer tube being pressed by the larger spring and selectively sliding toward the lancet cover and away from the inner tube, when a fingertip pushes on the lancet cover and hence the outer tube, the teeth on the inner rim of the outer tube forcing the protrusion of the connecting rod to rotate and triggering a release of the lancet holder, the lancet holder moving toward the fingertip; and a lancet holder (35) located in the interior of a second end of the outer tube and having a lanset cover slope, the lancet is located in the lancet holder, a lancet holder engaging with the

connecting rod, the lancet holder sliding along the interior of the outer tube without rotating as the connecting rod rotates, outer tuber slope of the outer tube engaging with the lancet cover slope on the lancet cover and selectively adjusting a depth of the lancet; and an upper protective cover (11) connected to the lower protective cover and having: an electronic circuit board (14) located on an interior thereof and analyzing an electrochemical reaction of the test strip with the bioanalyte; an LCD monitor (15) electrically connected to the electronic circuit board and displaying results from the electrochemical reaction of the test strip with the bioanalyte; and an opening (12), the test strip is removably inserted into the opening, the lancing device is located in an end of the upper housing; a monitor cover having: a protective cap (16) connected to the upper protective cover and the lower protective cover and having a hole and a protrusion (344) located on an inner rim of the hole; and a lancet cover (17) located on an interior of the protective cap and having a plurality of grooves (172), a lance cover slope (173), and a hole (171), the protrusion of the protective cap is located in a selected groove of the plurality of grooves, the lance cover slope engaging the outer tube and selectively adjusting the depth of the lancet.

Other embodiments of the present invention include a communication port located on the upper protective cover and the lower protective cover and electrically connected to the electronic circuit board.

The primary reference to Cunningham et al. teaches a solenoid valve (74) driving a piston (64) to move in a housing (62), a lance holder (66) moved outwardly from the housing by the piston and pressed by into the housing by a return spring (68).

Cunningham et al. do not teach an inner tube (31) connected to the lower protective cover and having inner tube teeth (313); a connecting rod (34) inserted into an interior of the inner tube and having a protrusion (344); the smaller spring biasing the connecting rod outwardly from the interior of the inner tube; the inner tube teeth engaging with and forcing the connecting rod to rotate within the inner tube as the connector rod moves axially within the inner tube; an adapter (33) located between the smaller spring and the connecting rod, the adapter connecting the connecting rod to the smaller spring; the connecting rod, the adapter and the

smaller spring are located in the interior of the outer tube; the protrusion of the connecting rod engaging the outer tube teeth and the inner tube teeth; nor do Cunningham et al. teach the outer tube being pressed by the larger spring and selectively sliding toward the lancet cover and away from the inner tube.

The secondary reference to Boecker et al. teaches a universal diagnostic platform and is cited for teaching a communication port.

Boecker et al. do not teach an inner tube (31) connected to the lower protective cover and having inner tube teeth (313); a connecting rod (34) inserted into an interior of the inner tube and having a protrusion (344); the smaller spring biasing the connecting rod outwardly from the interior of the inner tube; the inner tube teeth engaging with and forcing the connecting rod to rotate within the inner tube as the connector rod moves axially within the inner tube; an adapter (33) located between the smaller spring and the connecting rod, the adapter connecting the connecting rod to the smaller spring; the connecting rod, the adapter and the smaller spring are located in the interior of the outer tube; the protrusion of the connecting rod engaging the outer tube teeth and the inner tube teeth; nor do Boecker et al. teach the outer tube being pressed by the larger spring and selectively sliding toward the lancet cover and away from the inner tube.

The secondary reference to LeVaughn et al. teaches a lancing device having a releasable connector and is cited for teaching a triangular protrusion.

LeVaughn et al. do not teach an inner tube (31) connected to the lower protective cover and having inner tube teeth (313); a connecting rod (34) inserted into an interior of the inner tube and having a protrusion (344); the smaller spring biasing the connecting rod outwardly from the interior of the inner tube; the inner tube teeth engaging with and forcing the connecting rod to rotate within the inner tube as the connector rod moves axially within the inner tube; an adapter (33) located between the smaller spring and the connecting rod, the adapter connecting the connecting rod to the smaller spring; the connecting rod, the adapter and the smaller spring are located in the interior of the outer tube; the protrusion of the connecting rod engaging the outer tube teeth and the inner tube teeth; nor do LeVaughn et al. teach the outer tube being pressed by the larger spring and selectively sliding toward the lancet cover and away from the inner tube.

Even if the teachings of Cunningham et al., Boecker et al., and LeVaughn et al. were combined, as suggested by the Examiner, the resultant combination does not suggest: an inner tube (31) connected to the lower protective cover and having inner tube teeth (313); a connecting rod (34) inserted into an interior of the inner tube and having a protrusion (344); the smaller spring biasing the connecting rod outwardly from the interior of the inner tube; the inner tube teeth engaging with and forcing the connecting rod to rotate within the inner tube as the connector rod moves axially within the inner tube; an adapter (33) located between the smaller spring and the connecting rod, the adapter connecting the connecting rod to the smaller spring; the connecting rod, the adapter and the smaller spring are located in the interior of the outer tube; the protrusion of the connecting rod engaging the outer tube teeth and the inner tube teeth; nor does the combination suggest the outer tube being pressed by the larger spring and selectively sliding toward the lancet cover and away from the inner tube.

It is a basic principle of U.S. patent law that it is improper to arbitrarily pick and choose prior art patents and combine selected portions of the selected patents on the basis of Applicant's disclosure to create a hypothetical combination which allegedly renders a claim obvious, unless there is some direction in the selected prior art patents to combine the selected teachings in a manner so as to negate the patentability of the claimed subject matter. This principle was enunciated over 40 years ago by the Court of Customs and Patent Appeals in In re Rothermel and Waddell, 125 USPQ 328 (CCPA 1960) wherein the court stated, at page 331:

> The examiner and the board in rejecting the appealed claims did so by what appears to us to be a piecemeal reconstruction of the prior art patents in the light of appellants' disclosure. ... It is easy now to attribute to this prior art the knowledge which was first made available by appellants and then to assume that it would have been obvious to one having the ordinary skill in the art to make these suggested reconstructions. While such a reconstruction of the art may be an alluring way to rationalize a rejection of the claims, it is not the type of rejection which the statute authorizes.

The same conclusion was later reached by the Court of Appeals for the Federal Circuit in Orthopedic Equipment Company Inc. v. United States, 217 USPQ 193 (Fed.Cir. 1983). In that decision, the court stated, at page 199:

> As has been previously explained, the available art shows each of the elements of the claims in suit. Armed with this information, would it then be non-obvious to this person of ordinary skill in the art to coordinate these elements in the same manner as the claims in suit? The difficulty which attaches to all honest attempts to answer this question can be attributed to the strong temptation to rely on hindsight while undertaking this evaluation. It is wrong to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit. Monday morning quarterbacking is quite improper when resolving the question of non-obviousness in a court of law.

In In re Geiger, 2 USPQ2d, 1276 (Fed.Cir. 1987) the court stated, at page 1278:

> We agree with appellant that the PTO has failed to establish a *prima facie* case of obviousness. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination.

Applicant submits that there is not the slightest suggestion in either Cunningham et al., Boecker et al., or LeVaughn et al. that their respective teachings may be combined as suggested by the Examiner. Case law is clear that, absent any such teaching or suggestion in the prior art, such a combination cannot be made under 35 U.S.C. § 103.

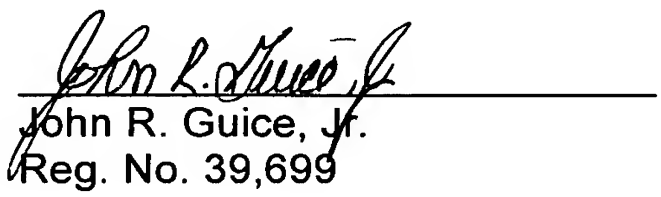
Neither Cunningham et al., Boecker et al., nor LeVaughn et al. disclose, or suggest a modification of their specifically disclosed structures that would lead one having ordinary skill in the art to arrive at Applicant's claimed structure. Applicant

hereby respectfully submits that no combination of the cited prior art renders obvious Applicant's new claims.

Summary

In view of the foregoing amendments and remarks, Applicant submits that this application is now in condition for allowance and such action is respectfully requested. Should any points remain in issue, which the Examiner feels could best be resolved by either a personal or a telephone interview, it is urged that Applicant's local attorney be contacted at the exchange listed below.

Respectfully submitted,

Date: July 14, 2006 By: 

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THE COMPACT STRUCTURE OF A NEW BIOSENSOR MONITOR

BACKGROUND OF THE INVENTION

(a) Field of the invention

This invention discloses the ~~compact structure~~ design of a ~~new~~ biosensor monitor with a built-in lancing device for the convenience of the diabetic patients. ~~This new portable structure comprises of a two-in-one design of a biosensor monitor for the simultaneous measurement of blood glucose, uric acid and cholesterol as well as a blood collection device with a needle.~~

(b) Description of the Prior Art

All diabetic patients generally require a glucose monitor and a lancing device. ~~the conventionally available biosensor monitors generally comprises of a monitor and a blood lancer which collects a tiny drop of blood by means of piercing a sharp needle into the finger or arm.~~ Although ~~they~~ both are ~~designed to be~~ portable, however, it requires more box space to put in both the monitor and blood lancer, making it rather bulky and inconvenient to carry around. Sometimes the lancing device is not present or lost, when it is time to perform a glucose measurement. Furthermore, ~~the operation of~~ to use a conventional ~~blood lancer~~ lancing

device requires two hands, one hand for triggering the lancing device to prick onto the fingertip of the other hand.~~and another one for needle puncture onto the right spot of the skin.~~ Such conventional design of the monitor and the ~~blood lancer~~ lancing device~~includes~~ means two separate individual items, resulting in higher costs and ~~less portability~~ packaging space. Moreover, the blood collection process by such ~~blood lancer~~ lancing device with both hands is rather in inconvenient. Therefore, a new monitor with built-in lancing device to reduce cost and space to pack will be great niche for diabetics so that they won't leave home without the lancing device. ~~two in one design to include a blood lancer to reduce costs, and hence enhanced portability, will be a great niche for sales promotion in the market where competition is very keen.~~

SUMMARY OF THE INVENTION

It is therefore the objective of this new design to provide a mechanism with the monitor and blood lancer in one piece, small in size and only one finger ~~operation only~~ to operate, which will be free from the inconvenience and d~~isadvantages~~ drawbacks associated with the conventional biosensor device.

The mechanical structure of this ~~two-in-one device~~ monitor ~~comprises of a housing~~ within which there is a circuit board with a receiver slot for

the test strip to be inserted in. Signals received from the reaction of the reagent on the test strip with the applied blood will be analyzed via the built-in CPU (Central Processing Unit) and shown on the LCD (Liquid Crystal Display) screen and, or, be transmitted through the communication port (USB, Serial or Parallel Port) to the computer for ~~internet server by mobile phone for further~~ data acquisition and analysis. This ~~two-in-one structure~~ monitor also houses a ~~blood lancer~~ lancing device, which composes of a number of parts and springs, to pierce the ~~sharp~~ needle of the lancet into the skin for a tiny drop of blood. This lancing device can be installed a disposable lance~~lancer fits a disposable needle, for single use only, and r~~. Replacing the used needle with a new one automatically reloads the ~~needle~~ lancing device ready to be triggered for blood inoculation, upon the touch one finger only. With this ~~unique two-in-one of~~ structural design, blood specimen can be easily collected with the touch of, say, a finger onto the ~~lancer~~ lancing device to trigger the release of the ~~needle~~lancet, and be applied onto the reagent of the test strip to determine ~~its~~ the results of its electrochemical reaction through the measurement of electrical current or voltage which will then be processed via the built-in CPU to display on the LCD screen.~~, and, or, be transmitted via wireless communication to a server, or to a linked~~

~~computer for further data storage and analysis.~~

BRIEF DESCRIPTION OF THE DRAWINGS

The ~~two-in-one~~ structure of the present invention may be more readily understood by one skilled in the art with reference to the following detailed drawings, wherein like elements are designated by identical reference numbers throughout the several views, and in which:

Fig. 1 is a schematic view of the ~~two-in-one~~ biosensor monitor pursuant to the teachings of the present invention, illustrating the test strip to be inserted into the monitor ~~and a prompt icon displayed on the monitor LCD screen upon inserted of the test strip~~.

Fig. 2 illustrates the top view of the positional relationship of the several components of the biosensor monitor.

Fig. 3 illustrates the side view of the positional relationship of the several components of the biosensor monitors.

Fig. 4 is the cross-sectional view of the ~~several~~ components of the ~~lancer~~ lancing device when the needle is in the free, unloaded state.

Fig. 5 is the cross-sectional view of the several components of the ~~lancer~~ lancing device when the ~~needle~~ lancing device is loaded and ready to trigger for the release of the ~~needle~~ lancet.

Fig. 6 is the cross-sectional view of the ~~several~~ components of the

~~lancer when the lancer~~ lancing device is triggered and the ~~needle~~ lancet is released to its most forward position.

Fig. 7 illustrates the exploded view of some of the ~~several~~ components of the ~~lancer~~ lancing device.

Fig. 8 illustrates the relative angular position of the ~~several~~ two components of the ~~lancer~~ lancing device.

Fig. 9 is the top view of the positional relationship of the ~~several~~ components of the monitor with the protective cap and ~~needle~~ lancet cover ~~of the needle~~.

Fig. 10 is the top sectional view of the relative position of the protective cap and the ~~needle~~ lancet cover, ~~demonstrating~~ showing the mechanism for the adjustment of the protective cap for ~~several~~ different depth of ~~the needle~~ lancet inoculated into the skin for different amount of blood drop.

Fig. 11 is the side view of the protective cap, showing the ~~guide~~ way to fix the ~~needle~~ lancet cover in different position for different ~~needle~~ depth of penetration into the skin.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings in detail, Fig. 1, the schematic view of the ~~two-in-one~~ biosensor monitor pursuant to teachings of the present

invention, shows a test strip 20 into the opening 12 on the upper protective cover 11 under which an ~~printed~~ electronic circuit board 14 is placed to measure the electrochemical response of the test strip with the added drop of blood, and on which a LCD screen 15 displays the results of the processed signals from the circuit board 14, and on which a communication port (USB, serial or parallel) 13 transmits the processed signals ~~via mobile phone to the internet server~~ to the computer for data acquisition and analysis. Connected to this upper protective cover 11 is a protective cap 16 for the ~~needle~~ lancet, not shown, on which there sits a ~~needle~~ lancet cover 17. To have more insight into the mechanism of the monitor 10, Fig. 2 illustrates the positional relationship of the several components of the monitor. A ~~couple~~ number of components constitute ~~a~~ ~~lancer~~ the lancing device 30 situated inside the upper protective cover 11. A ~~needle~~ lancet 40 sits on the holder 35~~on the lancer~~ in the lancing device 30. This Fig.2 gives a better view of the ~~needle~~ lancet cover 17 and a protective cover 16 and the ~~lancer~~ lancing device 30, while Fig.3 gives the side cross sectional view of the monitor 10, the ~~lancer~~ lancing device 30 and the protective cover 16 with the ~~needle~~ lancet cover 17.

Fig. 4, 5, and 6 illustrate the cross-sectional view of the ~~lancer~~ lancing device 30 with the ~~needle~~ lancet 40 in three different operational modes.

Fig. 4 shows the positional relationship of the ~~several~~ components of the ~~lancer~~ lancing device in the free relaxed state, wherein the spring 32 has neither compressive nor tensional stress. Whereas, Figs 5 gives the positional relationship of the ~~several~~ components of the ~~lancer~~ lancing device 30 when the spring 32 is fully compressed to its limit as a ~~new~~ ~~needle~~ lancet 40 is installed on, ready to release the ~~needle~~ lancet 40. As soon as the needle cover 17 is pressed by the slightly touch of a finger tip on the lancet cover 17, the lancet cover 17 will further push the outer tube 36~~, neighboring to and engaging with the needle cover 17, will be pushed~~ to the left to trigger the rotation of the connecting rod 34 which in turn trigger the release of the ~~needle~~ lancet holder 35 and the lancet 40 and ~~its~~ other connecting components such as ~~the needle receiver 35,~~ the connecting rod 34 and the adaptor 33, by the compressive force of the spring 32. The inner tube 31 is stationary and sits onto the lower protective cover 18 by the two posts 39 which fits into the opening space next to the left rear end of the inner tube 31, while the outer tube 36 slides along the inner tube 31, guided by the ~~protrusion~~ teeth 363, on the inner rim of the outer tube 36 which fits well into the opening slot 312 of the inner tube 31. The outer tube 36 can slide to the left by the push of the neighboring needle cover 17 to the right and ~~will~~can slide to the right

position by the compressive force in the large spring 38. The sliding movement of the outer tube 36 only happens when the ~~needle~~ lancet 40 is ~~about to be trigger~~ ready for release. The inner tube 31 holds well to one end of the small spring 32, while the adaptor 33 ~~holds~~ locks well the other end of the small spring 32, and hence the adaptor 33 ~~in non-rotatable~~can not rotate. Although the adaptor 33 ~~fits with~~ connects to the connecting rod 34, nevertheless, ~~the~~ a good tolerance between them allows the connecting rod 34 to rotate freely against the adaptor 33. This connecting rod 34 ~~fits tightly~~ engages with the ~~needle receiver~~ lancet holder 35 and as they~~ir combination~~ moves to the left, the connecting rod 34~~it simultaneously~~ will ~~somewhat~~ rotate against the lancet holder 35 because the triangular protrusion 344 onf the connection rod 34 will be guided to rotate by the teeth 313 of the inner tube 31, which can better be understood by referring to Fig. 7 and Fig.8. The teeth 313 of the inner tube 31 will guide and force the triangular protrusion 344 of the connecting rod 34 to rotate relative to the inner tube 31, as the connecting rod 34 moves toward the inner tube 31, the teeth 362, which lies inside the inner wall of the outer tube 36, will further guide and force the triangular protrusion to rotate and stay either at the stop 364 or the extreme position 365, depending upon the relative position of the

triangular protrusion 344 with the teeth 313. When the triangular protrusion stays at the location 364, the lancet holder 35 and the lancet ~~needle~~ 40 and the connecting rod 34 combination are in the position ready for the ~~rode~~ lancet 40 to launch ~~the~~ for inoculation for blood, just like the ~~r~~mode in Fig.5. ~~Moreover~~Furthermore, when the triangular protrusion 344 stays at the location 365, the connecting rod 34 and the ~~needle~~ lancet 40 combinations are at the state of being after launch, just like the mode in Fig. 6. Fig.9, 10 and 11 illustrate~~s~~ the mechanism of the ~~needle~~lancet cover 17 and the protective cover 16, with which the ~~needle~~ lancet cover 17 can rotate relative to the protective cover 16 to adjust the depth of the needle 40 piercing into the skin by the engaging slope 364 of the tube 36 with the slope 173 of the ~~needle~~ lancet cover 17, which has a hole 171 for the needle in front of the lancet 40 to go through and a number of grooves 172 for the protrusion 161 on the inner wall of the protective cover 16, as shown in Fig. 10 and 11, to define the depth of ~~needle~~ lancet 40 into the skin, which then results in different amount of blood ~~inoculation~~.